** Kentucky Medicaid Pharmacy Provider Notice #279 – Paxlovid Physician Protocol For Medicaid Members **

****This applies to both Fee-For-Service Medicaid and the Managed Care Organizations****

August 16th, 2022

Attached to this notice you will find a signed Physician Protocol issued by the Department for Medicaid Services (DMS) Medical Director, Judith Theriot. Please note, this protocol should be used ONLY when dispensing Paxlovid to qualifying Kentucky Medicaid members.

Pharmacies should input Dr. Theriot's National Provider ID (NPI) in the Prescriber ID field. Therefore, the Pharmacist/Pharmacy NPI should not be used in the Prescriber ID field. **All noted procedures must be followed to receive reimbursement**.

Thank you for assisting Kentucky Medicaid members with increased access to Paxlovid. DMS remains committed to ensuring that members receive the appropriate care to treat and prevent the spread of COVID-19.

For any additional information or questions that you may have, please contact Magellan Medicaid Administration at kyproviders@magellanhealth.com for Fee-for-Service members or the Kentucky MedImpact team at kymcopbm@medimpact.com for Managed Care Organization (MCO) members.

Sincerely,

ShaLeigh Hammons

ShaLeigh Hammons, CPhT

Account Manager I

kyproviders@magellanhealth.com

Kentucky Medicaid Fee-for-Service Pharmacy Program's Contact Information		
Clinical Support Center	1-800-477-3071 Sunday – Saturday 24 hours a day	Please contact the Clinical Support Center to request a prior authorization (PA) or to check the status of a request.
Pharmacy Support Center	1-800-432-7005 Sunday – Saturday 24 hours a day	Please contact the Pharmacy Support Center when claims assistance is required. Timely filing, lock-in, and early refill (ER) overrides can be obtained through this Call Center.
Provider Services	1-877-838-5085 Monday – Friday 8:00 a.m. – 4:30 p.m.	Please contact Provider Services if you have questions about enrollment or when updating your license or bank information.
Member Services	1-800-635-2570 Monday – Friday 8:00 a.m. – 5:00 p.m.	Please contact Member Services if you are a member or if you as the provider have questions regarding the member's benefits or eligibility coverage dates.

SARS-CoV-2 THERAPEUTICS PROTOCOL

PURPOSE

This protocol specifies the criteria and procedures for pharmacists to initiate the dispensing of the oral SARS-CoV-2 therapeutic nirmatrelvir/ritonavir (Paxlovid) for the treatment of COVID-19 under the FDA's emergency use authorization.

IMPORTANT NOTE

Please note, this protocol has been signed below by Dr. Theriot, Medical Director at Kentucky Department for Medicaid Services. Hence, this signed protocol shall **only** be applicable for Medicaid beneficiaries.

CRITERIA

Pharmacists authorized to initiate the dispensing of oral Paxlovid according to the FDA's *Fact Sheet for Healthcare Providers: Emergency Use Authorization for Paxlovid*[1].

Inclusion criteria (all of the following must be met):

- 12 years of age and older weighing at least 40 kilograms
- Positive results of direct SARS-CoV-2 viral testing within the past 5 days through any of the following:
    - Documentation of a polymerase chain reaction (PCR) test conducted off-site
    - Results from a CLIA-waived PCR test, nucleic acid amplification test (NAAT) or rapid antigen detection test (RADT) ordered and conducted onsite as authorized by this protocol
    - Self-report of a positive home test result from an RADT.

  Note: antibody tests are NOT considered to be direct SARS-CoV-2 tests
- At high risk for progression to severe COVID-19, including hospitalization or death[2]
- Sufficient information available to assess renal and hepatic function
- Sufficient information available to assess for potential drug interactions

Exclusion criteria (any one of the following are met):

- Severe renal impairment (eGFR <30 mL/min)
- Severe hepatic impairment (Child-Pugh Class C)
- History of clinically significant hypersensitivity reactions to nirmatrelvir, ritonavir or any other components
- Co-administration with drugs highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious or life-threatening reactions, including:
    - alfuzosin, silodosin

[1] Available at: https://www.fda.gov/media/155050/download

[2] Available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html

  - pethidine (meperidine)
  - ranolazine
  - amiodarone, dronedarone, flecainide, propafenone, quinidine
  - colchicine
  - lurasidone, pimozide, clozapine
  - eplerenone, ivabradine
  - dihydroergotamine, ergotamine, methylergonovine
  - lovastatin, simvastatin
  - voclosporin
  - lomitapide
  - eletriptan, ubrogepant
  - finerenone
  - naloxegol
  - sildenafil when used for pulmonary arterial hypertension (PAH)
  - triazolam, oral midazolam
  - flibanserin
  - tolvaptan
- Co-administration with potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance, including:
  - apalutamide
  - carbamazepine, phenobarbital, primidone, phenytoin
  - lumacaftor/ivacaftor
  - rifampin
  - St. John's Wort
- Co-administration with other medications for which dosage adjustment would be necessary due to a potential drug interaction (Appendix 1)
- Patients requiring hospitalization due to severe or critical COVID-19
- Desire for pre-exposure or post-exposure prophylaxis against COVID-19

MEDICATIONS

This protocol authorizes pharmacists to initiate the dispensing of:

Medication	Dose	SIG	Notes
nirmatrelvir/ritonavir (Paxlovid)	300 mg nirmatrelvir (two 150 mg tablets) co-packaged with 100 mg ritonavir	BID x 5 days	eGFR ≥60 mL/min
nirmatrelvir/ritonavir (Paxlovid)	150 mg nirmatrelvir co-packaged with 100 mg ritonavir	BID x 5 days	eGFR ≥30 to <60 mL/min

PROCEDURES FOR INITIATION AND MONITORING OF THERAPIES

Paxlovid therapy initiation and monitoring will be individualized based on patient history and consideration of contraindications and precautions of therapy as outlined in the FDA's *Fact Sheet for Healthcare Providers: Emergency Use Authorization for Paxlovid*[3]. Pharmacists may utilize the authority granted under this protocol to order and conduct CLIA-waived SARS CoV 2 testing.

Pharmacists must have sufficient information to determine eligibility to receive Paxlovid:

- A list of all patient medications, including over-the-counter medications to screen for drugs with potentially serious interactions with Paxlovid (Appendix 1)
- Electronic or printed health records less than 12 months old, including the most recent reports of laboratory blood work to review for kidney or liver problems; or
- Information received from a consult with the patient's health care provider

After assessment of information and determination of eligibility to receive Paxlovid under this protocol (**i.e. patient meets all inclusion criteria and has no exclusion criteria from above**), pharmacists are authorized to initiate the dispensing of Paxlovid as outlined in the Medication Table above.

EDUCATION REQUIREMENTS

Pharmacists must communicate to the patient and/or caregiver information consistent with the *"FACT SHEET FOR PATIENTS, PARENTS, and CAREGIVERS"*[4] and provide them with a copy prior to dispensing.

- Inform patients that hypersensitivity reactions have been reported, even after one dose
- Advise patients to discontinue the drug and inform their (Health Care Provider) HCP of the first sign of an allergic reaction
- Inform patients that Paxlovid may interact with some drugs and is contraindicated with some drugs
- Alert patients of the importance of completing the full 5-day treatment course
- Advise persons who are able to become pregnant of the need to abstain from sexual activity while taking Paxlovid or use a barrier method of contraception
- Inform patients about the possibility of "rebound COVID" after Paxlovid and steps they should take if this occurs[5]

[3] Available at: https://www.fda.gov/media/155050/download

[4] Available at: https://www.fda.gov/media/155051/download

[5] Available at: https://emergency.cdc.gov/han/2022/pdf/CDC_HAN_467.pdf

DOCUMENTATION

Pharmacists will document via prescription record each person who receives Paxlovid under this protocol, including:

- Documentation of the assessment of renal and hepatic function, and patient medication list for contraindications and drug interactions
- Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication
- Documentation that the individual receiving Paxlovid was provided with the required education pursuant to this protocol
- Documentation of mandatory reporting of any serious adverse events and medication errors potentially related to PAXLOVID within 7 calendar days from the healthcare provider's awareness of the event, using FDA Form 3500[6]. Serious adverse events are defined as:
    - Death
    - A life-threatening adverse event
    - Inpatient hospitalization or prolongation of existing hospitalization
    - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
    - A congenital anomaly/birth defect
    - Other important medical event, which may require a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly

NOTIFICATION

Pharmacist(s) shall ask all persons receiving Paxlovid under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the medications dispensed under the protocol to the identified primary care provider within two (2) business days.

Any individual affirmatively stating that the individual does not have a primary care provider may still receive Paxlovid under this protocol provided all other applicable requirements of the protocol are met.

[If directed by the authorizing prescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of persons receiving Paxlovid under this protocol within 7 days of initiating dispensing]

TERMS

This protocol is effective as of the date all parties execute the document. It shall remain in effect for a period of one year and shall automatically renew for successive one-year periods unless otherwise terminated by any party, with or without cause. Any termination without cause shall

[6] Available at: https://www.fda.gov/medwatch/report.htm

require prior notice to all parties of no less than sixty days.

SIGNATURES

Judith Ann Theriot, MD, CPE
Prescriber Name

August 10, 2022
Date

Judith Ann Theriot, MD, CPE
Prescriber Signature

NPI 1811990476